Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jul 2026

The effects of curcumin on the cardiopulmonary efficacy in subjects with central obesity: A Randomized, Double-Blind, Placebo-Controlled Trial

Protocol summary

Study aim
To determine the effects of curcumin on cardiopulmonary efficacy in subjects with central obesity

Design
This is a triple blinded randomized controlled clinical trial phase II with a parallel group design of 50 subjects, in which a random number table was used for randomization.

Settings and conduct
Subjects include individuals with central obesity who refer to Persian cohort of the Mashhad University of Medical Sciences. All volunteers, care providers and statistician are blinded after assignment to intervention. So that, the supplements containers were coded as A and B by a non-researcher person and remained confidential until data analysis. The placebos are similar to the supplements regarding the weight and color. Subjects will be randomly assigned to one of two study groups and will receive 500 mg of curcumin or placebo over 56 days. Fasting blood samples are taken from all individuals before and after the intervention. Cardiopulmonary exercise testing (CPET) will be measured for all participants by a trained expert and physician before and after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Aged 18-65 years old, Subjects with central obesity based on the US National Cholesterol Education Programme Adult Treatment Panel III (NCEP ATP III) guidelines; Exclusion criteria: History of systemic diseases, History of cardiac ischemia, Pregnancy, Breastfeeding, Hepatic failure, Hepatic failure, Biliary obstruction

Intervention groups
The drug group (n = 25), will receive the curcumin and the control group (n = 25), will take the placebo of the same shape, weight and color with the drug at a dose of 500 mg/day over 56 days.

Main outcome variables
maximal oxygen consumption (V̇O2max)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210413050958N6**
Registration date: **2022-07-31, 1401/05/09**
Registration timing: **prospective**

Last update: **2022-07-31, 1401/05/09**
Update count: **0**

Registration date
2022-07-31, 1401/05/09

Registrant information

Name
Maryam Saberi-Karimian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3764 3808

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-01, 1401/08/10

Expected recruitment end date
2025-03-20, 1403/12/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effects of curcumin on the cardiopulmonary efficacy in subjects with central obesity: A Randomized, Double-Blind, Placebo-Controlled Trial

Public title
Effect of curcumin on cardiopulmonary efficacy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Signed informed consent form Aged 18-65 years old Subjects with central obesity based on NCEP-ATP III guidelines
Exclusion criteria:
History of systemic diseases History of cardiac ischemia Pregnancy Breastfeeding Hepatic failure Biliary obstruction
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **25**
Randomization (investigator's opinion)
Randomized
Randomization description
The statistician generates a random allocation sequence using the block randomization method. So that blocks with size 4 and 2 of the combination of letters A and B (ABBA, ABAB, AABB, BAAB, BBAA, BABA), (AB and BA) are selected to the required number using a table of random numbers and individuals are assigned to groups according to the created sequence. Subjects are divided into one of two intervention/control groups using a table of random numbers, so that who enrolled the trial can select a sealed envelope with random allocation sequence to the intervention or control group. An expert outside the research team blinds the drugs. The executive team register the subjects and assign them to the intervention. All volunteers, the executive team, and the statistical analyst will be blinded by the interventions.
Blinding (investigator's opinion)
Double blinded
Blinding description
The random allocation sequence is made using the table of random numbers. Sequentially numbered sealed envelopes are used to implement the random allocation sequence which opened by a person not involved in the project. The participants, care providers and statistician are blinded after assignment to intervention. So that, the powders bottles are coded by a non-researcher person and remain confidential until data analysis. Moreover, In addition, placebo powder is similar to supplement powder in shape, weight and color.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Ghoreishi buildings, Daneshgah Ave.
City
Mashhad
Province
Razavi Khorasan
Postal code
99199-91766
Approval date
2022-05-24, 1401/03/03
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1401.212

Health conditions studied

1

Description of health condition studied
central obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
maximal oxygen consumption (V̇O2max)
Timepoint
Before the intervention and 8 weeks after taking supplement or placebo
Method of measurement
cardiopulmonary exercise testing

Secondary outcomes

1

Description
ratio of minute ventilation to carbon dioxide output (VE/V

CO2)

Timepoint

Before the intervention and 8 weeks after taking supplement or placebo

Method of measurement

cardiopulmonary exercise testing (CPET)

2

Description

Dead-space ventilation (Vd/Vt)

Timepoint

Before the intervention and 8 weeks after taking supplement or placebo

Method of measurement

cardiopulmonary exercise testing (CPET)

3

Description

alveolar-arterial oxygen pressure gradient [P(A-a)O2]

Timepoint

Before the intervention and 8 weeks after taking supplement or placebo

Method of measurement

cardiopulmonary exercise testing (CPET)

4

Description

Blood pressure

Timepoint

Before the intervention and 8 weeks after taking supplement or placebo

Method of measurement

sphygmomanometer

5

Description

Fasting blood sugar

Timepoint

Before the intervention and 8 weeks after taking supplement or placebo

Method of measurement

Auto analyzer

6

Description

Lipid profile (Total cholestrol, Triglyceride, High density lipoprotein, Low density lipoprotein)

Timepoint

Before the intervention and 8 weeks after taking supplement or placebo

Method of measurement

Auto analyzer

7

Description

Anaerobic threshold

Timepoint

Before the intervention and 8 weeks after taking supplement or placebo

Method of measurement

cardiopulmonary exercise testing (CPET)

8

Description

Peak heart rate

Timepoint

Before the intervention and 8 weeks after taking supplement or placebo

Method of measurement

cardiopulmonary exercise testing (CPET)

9

Description

Heart rate reserve

Timepoint

Before the intervention and 8 weeks after taking supplement or placebo

Method of measurement

cardiopulmonary exercise testing (CPET)

10

Description

Peak work

Timepoint

Before the intervention and 8 weeks after taking supplement or placebo

Method of measurement

cardiopulmonary exercise testing (CPET)

11

Description

Ventilator reserve

Timepoint

Before the intervention and 8 weeks after taking supplement or placebo

Method of measurement

cardiopulmonary exercise testing (CPET)

12

Description

Respiratory frequency

Timepoint

cardiopulmonary exercise testing (CPET)

Method of measurement

cardiopulmonary exercise testing (CPET)

Intervention groups

1

Description

The treatment group (n= 25) including subjects with central obesity based on NCEP-ATP III. Curcumin (C3 complex) at a dose of 500 mg/day plus 5 mg piperine is taken orally over 8 weeks purchased from Sami Labs LTD

(Bangalore, India) in the intervention group.

Category

Treatment - Drugs

2

Description

The control group includes subjects with central obesity based on NCEP-ATP III. Placebo at a dose of 500 milligram per day containing 5 mg of piperine too that purchased from Sami Labs LTD (Bangalore, India) and are the same shape and color with curcumin that is received orally by control group over 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Mahmoud MohammadZadeh Shabestari

Street address

Imam Reza Hospital, Ibn Sina Street

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Maryam Saberi-Karimian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Maryam Saberi-Karimian

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Raw data will be shared upon a reasonable request from the corresponding author.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Following a reasonable request, deidentified data will be shared.
When the data will become available and for how long
After publication of paper(s) upon a reasonable request
To whom data/document is available
Study PI and executive team
Under which criteria data/document could be used
For reasonable research or clinical purpose
From where data/document is obtainable
Maryam Saberi-Karmian
What processes are involved for a request to access data/document
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Comments